K963030 APR 11 1997

## 510(k) Summary

| | |
|---|---|
| Device Proprietary Name: | Leibinger® IMF Screw |
| Device Common Name: | Small Bone Screw |
| Classification Name: | Intraosseous Fixation Screw or Wire<br>21 CFR 872. 4880<br>76 DZL |
| Name of Submitter: | Howmedica Leibinger Inc. |
| Contact Person: | Kristyn R. Waski<br>QA/RA Engineer<br>Howmedica Leibinger Inc.<br>14540 Beltwood Pkwy., East<br>Dallas, TX 75244<br>Telephone: (972) 392-3636 x266<br>Fax: (972) 392-7258 |
| Date Prepared: | March 12, 1997 |

Summary:

This submission describes a small bone screw intended for use in temporary maxillomandibular fixation to provide indirect stabilization of the maxilla, mandible, or both. The Leibinger® IMF Screw is 2.0 mm in diameter and ranges from 10.5-18.5 mm in total length (6-14 mm in threaded length). There is a hole in the screw head through which a wire can be passed to fix the maxilla and mandible. The device is for single use only.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Unisplint Dental Arch Bar (K820944); the Synthes Minihook and Cortical Screw (K# Unknown); the Synthes Cortical Bone Screw (K912932); and the Leibinger®-Luhr® Small Mandibular Bone Screws (K963740). The Dental Arch Bars, Minihook and Cortical Screw and Cortical Bone Screw are intended for use in maxillomandibular fixation to provide stabilization of fractures of the maxilla, mandible, or both. The Leibinger® IMF Screw and the Synthes Cortical Bone Screw can both be manufactured from commercially pure titanium; the Leibinger® IMF Screw and the Leibinger®-Luhr® Small Mandibular Bone Screws can both be manufactured from Ti(6Al,4V). The basic operational principle is similar for the cortical screw and arch bar devices.